IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DORI AMBER JORDAN, Plaintiff, vs. BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG and BAYER OY, Defendants.	COMPLAINT AND DEMAND FOR JURY TRIAL CIVIL CASE NO.:

Plaintiff, by and through the undersigned counsel, through her Complaint hereby alleges against Bayer HealthCare Pharmaceuticals, Inc., Bayer Pharma AG and Bayer OY the following:

INTRODUCTION

1. Plaintiff brings this case against Defendants for injuries caused by the Mirena intrauterine device ("IUD") because it caused physical injury after it was properly inserted by a healthcare provider who followed Defendants' instructions and/or training.

THE PARTIES

2. At all relevant times, Plaintiff was a citizen and resident of North Carolina, now residing in Winston-Salem, North Carolina.

3. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the state of Delaware with its primary place of business in Wayne, New Jersey.

4. Defendant is in the business of designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing prescription drugs and women's healthcare products, including the Mirena IUD.

5. Defendant conducts business in North Carolina and this district, including selling its Mirena IUD.

6. Defendant was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc. and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

7. Defendant is the holder of the approved New Drug Application ("NDA") for the Mirena IUD.

8. Defendant regularly and routinely conducts business in North Carolina and this jurisdiction through the sale of Mirena and other products.

9. Upon information and belief, Defendant BAYER PHARMA AG f/k/a BAYER SCHERING PHARMA AG ("BAYER PHARMA AG") is, and at all relevant times was, a global pharmaceutical corporation organized under the laws of Germany.

10. Upon information and belief, at all relevant times, Defendant BAYER PHARMA AG has transacted and conducted business in the State of North Carolina and derived substantial revenue from interstate commerce.

11. Upon information and belief, at all relevant times, Defendant BAYER PHARMA AG expected or should have expected that its acts would have

consequences within the United States of America, and the State of North Carolina in particular and derived substantial revenue from interstate commerce.

12. Upon information and belief, and at all relevant times, Defendant BAYER PHARMA AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute MIRENA® for use as an intrauterine contraceptive device.

13. Upon information and belief, Defendant BAYER PHARMA AG was also formerly known as Schering AG and is the same corporate entity as Schering AG.

14. Upon information and belief, effective July 1, 2011, BAYER SCHERING PHARMA AG was renamed BAYER PHARMA AG. BAYER PHARMA AG is the same corporate entity as BAYER SCHERING PHARMA AG.

15. Upon information and belief, Defendant BAYER OY is organized and exists under the laws of Finland and is headquartered at Pansiontie 47 20210 Turku, Finland.

16. Upon information and belief, Defendant BAYER OY is the current owner of the trademark relating to MIRENA®.

17. Upon information and belief, at all relevant times, Defendant BAYER OY has transacted and conducted business in the State of North Carolina and derived substantial revenue from interstate commerce.

18. Upon information and belief, at all relevant times, Defendant BAYER OY expected or should have expected that its acts would have consequences within

the United States of America, and the State of North Carolina in particular and derived substantial revenue from interstate commerce.

19. Defendants Bayer HealthCare Pharmaceuticals, Inc., Bayer Pharma AG, and Bayer OY shall be referred to herein individually by name or jointly as "Defendants".

20. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, division, franchises, partners, joint venturers, and organizational unites of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

21. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, Mirena.

JURISDICTION AND VENUE

22. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $150,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as Plaintiff is a citizen of North Carolina, which is different from the states where Defendants are incorporated and have their principal places of business.

23. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

24. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. § 1391(c) and because a substantial part of the events giving rise to Plaintiff's claims occurred in this jurisdiction.

25. This action includes claims for injuries to Plaintiff caused by the insertion of a Mirena IUD and therefore should be transferred to Mult-District Litigation No. 2434 - *In Re: Mirena IUD Products Liability Litigation*, United States District Court for the Southern District of New York, the Honorable Cathy Seibel.

FACTUAL BACKGROUND

26. Mirena is an intrauterine contraceptive system that is designed to be inserted into the uterus by a healthcare provider during an office visit.

27. The Food and Drug Administration ("FDA") approved Defendants' NDA for Mirena in December 2000.

28. The Mirena IUD is approved to remain in the uterus for up to five years.

29. Mirena has a T-shaped polyethylene frame with a steroid reservoir that contains 52 mg of levonorgestrel.

30. Levonorgestrel is a prescription medication used as a contraceptive.

31. Mirena is intended to release 20 mcg of levonorgestrel each day.

32. Mirena does not necessarily release the intended amount. Rather, it releases approximately 20 mcg of levonorgestrel each day, and the daily amount decreases progressively over time.

33. The total serum concentration of levonorgestrel in women using Mirena has been measured as high as 332 mcg and as low as 52 mcg between one and two years after insertion.

34. The Defendants do not know why the serum concentration of levonorgestrel varies so widely in different users of Mirena.

35. It is generally known that long-term use of progestins, including levonorgestrel, results in a thinner uterine wall.

36. The Defendants do not know exactly how Mirena works, but it may thicken cervical mucus, thin the uterine lining, or inhibit sperm movement and reduce sperm survival, to prevent pregnancy.

37. The Mirena label warns that the device may perforate the uterus during insertion, but does not warn about rates of embedment or spontaneous perforation, migration, organ damage, infertility, or the risk of the need for surgical intervention, including after successful insertion.

38. The Mirena label describes perforation as an "uncommon" event.

39. Defendants knew or should have known that the risk of uterine embedment and perforation is increased until as long as six months post-partum, but failed to warn of this risk.

40. Defendants knew or should have known the magnitude of increased risk of embedment and perforation among lactating women, but failed to disclose this information.

41. Defendants have a history of overstating the efficacy of Mirena while understating its risks and safety concerns.

42. In or around December 2009, Defendants were contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC") regarding a consumer-directed program entitled "Mirena Simple Style Statements Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private setting by a representative from "Mom Central", a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendants.

43. This Simple Style program represented that Mirena use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined that these claims were unsubstantiated and, in fact, pointed out that Mirena's package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

44. The Simple Style program script also intimated that Mirena use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirena can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

45. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage if a woman becomes pregnant while using Mirena.

46. Finally, Defendants falsely claimed in this advertisement that Mirena required no compliance with a monthly routine.

47. Soon after the first sales of Mirena, and with increasing incidence up until the present, Defendants received notice of complications with the use of the IUD including embedment in the wall of the uterus, perforation of the uterus, and the need for surgical intervention after successful insertion.

48. The embedment, perforations, and the need for surgical removal, including after successful insertion, are caused by the defective design of Defendants' Mirena IUD.

49. Although Defendants received reports of embedment, perforation, organ damage, infertility, and the need for surgical removal, including after successful insertion, they failed to study the rate at which these injuries were occurring, and failed to disclose these risks and rates.

50. Defendants failed to issue warnings of the risks associated with the Mirena IUD that were commensurate with the risks of which they were aware, and Defendants concealed the knowledge it had of the risks from Plaintiff, her prescriber, the medical profession generally and from governmental regulatory bodies including the FDA.

51. Upon information and belief, on approximately April 4, 2011, Dr. Andrew Lewis at Valaoras & Lewis Obstetrics & Gynecology discussed placing a Mirena IUD in Plaintiff Dori Jordan. Dr. Lewis discussed the risks and benefits of the Mirena IUD. Because Defendants did not disclose the true risks of perforation, migration and embedment of the Mirena device to Dr. Lewis, nor did Defendants disclose the true risks of perforation, migration and embedment in the information given to Plaintiff, it was impossible for Dr. Lewis to adequately discuss the true risks and benefits of the Mirena IUD with Plaintiff. Consequently, it was impossible for Plaintiff to learn of the true risks of the Mirena IUD.

52. Plaintiff, after a consultation with Dr. Lewis, had the Mirena device implanted by Dr. Lewis on or about April 4,, 2011. The Mirena IUD implanted in Plaintiff remained in substantially the same condition between when it left Defendants' control and when it was implanted in Plaintiff. Dr. Lewis would not have implanted the Mirena in Plaintiff if Dr. Lewis knew of the true risks of the Mirena IUD. In other words, Dr. Lewis would not have implanted the Mirena device in Plaintiff if he knew the true rate of migration, embedment and perforation of the Mirena IUD.

53. Plaintiff would not have elected to have the Mirena IUD implanted in her if she knew of the true risks associated with the use of Mirena. In other words, Ms. Jordan would not have elected to have the Mirena device implanted in her if she knew the true rate of migration, embedment and perforation of the Mirena IUD.

54. By September 23, 2011, the Mirena IUD embedded in Ms. Jordan's uterus and had perforated halfway through the uterine wall and was half inside the uterus and half in the uterovaginal space. Upon information and belief, testing showed that the Mirena IUD had migrated and perforated her uterus, and was not located in the proper position. The Mirena IUD migrated and perforated Plaintiff's uterus because it was negligently and defectively designed. Defendants knew that the Mirena IUD was negligently and defectively designed when it left Defendants' control, and Defendants knew that it migrated, perforated and embedded at a higher rate than other IUDs on the market. Defendants did not disclose these facts to Dr. Lewis or Ms. Jordan.

55. Through no fault of her own, and no fault of her health care providers, on September 23, 2011 Plaintiff had the Mirena IUD surgically removed because it had embedded and perforated her uterus and was no longer located in the proper position. The surgery caused pain and suffering, financial loss and caused permanent injury to Plaintiff, including a scar.

CAUSES OF ACTION

COUNT I
STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT

56. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

57. Mirena was designed, manufactured, marketed, promoted, sold, and introduced into the stream of commerce by Defendants.

58. When it left the control of Defendants, the IUD was expected to, and did reach Plaintiff without substantial change from the condition in which it left Defendants' control.

59. The IUD was defective when it left Defendants' control and was placed in the stream of commerce, in that there were foreseeable risks that exceeded the benefits of the product and/or that it deviated from product specifications and/or applicable federal requirements, and posed a risk of serious injury and death.

60. Specifically, the device was more likely than other similar devices to embed, migrate, cause perforation, organ damage, or infertility, and require surgical removal, including after successful insertion.

61. The IUD was inserted into Plaintiff in substantially the same condition it was in when it left control of Defendants and any changes or modifications were foreseeable by Defendants.

62. Plaintiff and her healthcare providers did not misuse or materially alter the Mirena device.

63. As a direct and proximate result of the Plaintiff's use of the IUD, she suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

64. Defendants are strictly liable to Plaintiff for designing, creating, manufacturing, distributing, selling, and placing Mirena into the stream of commerce, and for all damages caused to Plaintiff by her use of Mirena because the product was defective.

65. Defendants' actions and omissions as alleged in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT II
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

66. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

67. The IUD was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by Plaintiff.

68. Defendants placed Mirena into the stream of commerce with wanton and reckless disregard for the public safety.

69. Mirena was defective in design in that, when it left Defendants' control, the foreseeable risks of the product exceeded the benefits associated with its design, and it was more dangerous than an ordinary consumer or ordinary healthcare provider would expect.

70. The foreseeable risks associated with Mirena's design include the fact that its design is more dangerous than a reasonably prudent consumer or

healthcare provider would expect when used in an intended or reasonably foreseeable manner.

71. Mirena was in an unsafe, defective, and inherently dangerous condition, which was unreasonably dangerous to its users and in particular, Plaintiff.

72. Mirena was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that Mirena was defective and unsafe, even when used as instructed.

73. The nature and magnitude of the risk of harm associated with the design of Mirena, including embedment, migration, perforation, organ damage, infertility, and the need for surgical removal, including after successful insertion, is high in light of the intended and reasonably foreseeable use of Mirena.

74. The risks of harm associated with the design of Mirena are higher than necessary and higher than with other forms of reversible contraception and other IUDs.

75. It is highly unlikely that Mirena users would be aware of the risks associated with Mirena through either warnings, general knowledge or otherwise, and Plaintiff specifically was not aware of these risks.

76. The design did not conform to any applicable public or private product standard that was in effect when Mirena left the Defendants' control.

77. Mirena's design is more dangerous than a reasonably prudent consumer would expect when used in its intended or reasonably foreseeable

manner as a reversible form of contraceptive. It was more dangerous than Plaintiff expected.

78. The intended or actual utility of Mirena is not of such benefit or to justify the risk of embedment, migration, perforation, organ damage, infertility, the need for surgical removal, including after successful intervention.

79. At the time the Mirena IUD left Defendants' control, it was both technically and economically feasible to have an alternative design that would not cause embedment, migration, perforation, organ damage, infertility, the need for surgical removal, including after successful insertion, or an alternative design that would have substantially reduced the risk of these injuries.

80. It was both technically and economically feasible to provide a safer alternative design that would have prevented the harm suffered by Plaintiff.

81. The unreasonably dangerous nature of Mirena caused serious harm to Plaintiff.

82. As a direct and proximate result of the Plaintiff's use of the Mirena IUD, which was designed, manufactured, marketed, promoted, sold, and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys'

fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT III
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

83. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

84. Defendants had a duty to warn Plaintiff and her healthcare providers of the risk of embedment, migration, perforation, organ damage, infertility and surgical removal of Mirena, including such risks after successful insertion.

85. Defendants knew, or in the exercise or reasonable care should have known, about the risk of embedment, migration, perforation, organ damage, infertility, and the need for surgical intervention, including after successful insertion.

86. Defendants failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of embedment, migration, perforation, organ damage, infertility, and the need for surgical removal, including after successful insertion, in light of the likelihood that its product would cause these injuries.

87. Defendants failed to update warnings based on information received from product surveillance after Mirena was first approved by the FDA and marketed, sold, and used in the United States and throughout the world.

88. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to women using Mirena after FDA approval.

89. When it left Defendants' control, the Mirena IUD was defective and unreasonably dangerous for failing to warn of the risk of embedment, migration, perforation, organ damage, infertility and the need for surgical removal, including after successful insertion.

90. Plaintiff used the IUD for its approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

91. Plaintiff and Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived their danger because the risks were not open or obvious.

92. Defendants, as the manufacturers and distributors of the device, are held to the level of knowledge of an expert in the field.

93. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

94. The warnings that were given by the Defendants failed to properly warn physicians of the risks associated with its device, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and through her physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

95. Defendants had a continuing duty to warn Plaintiff and her prescriber of the dangers associated with its product.

96. Had Plaintiff or her healthcare providers received adequate warnings regarding the risks associated with the use of the Mirena IUD, she would not have used it, but would instead have used other means for contraception.

97. As a direct and proximate result of the Plaintiff's use of the IUD and Plaintiff's reliance on Defendants' representations regarding the character and quality of the product and Defendants' failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT IV
NEGLIGENCE

98. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

99. Defendants had a duty to exercise reasonable and ordinary care in the design, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of Mirena into the stream of commerce, including a duty to assure that its product did not pose an undue risk of bodily

harm and adverse events, and to properly warn of all risks, and comply with federal requirements.

100. Defendants failed to exercise reasonable and ordinary care in the design, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Mirena into the stream of commerce in that Defendants knew or should have known that the product caused significant bodily harm and was not safe for use by consumers. Specifically, Defendants failed to properly and thoroughly:

a. Test Mirena before releasing it into the market;

b. Analyze the data resulting from the pre-marketing tests of Mirena;

c. Conduct sufficient post-market testing and surveillance of Mirena; and

d. Provide appropriate warnings for consumers and healthcare providers including disclosure of the known or potential risks or true or suspected rates of embedment, migration, perforation, organ damage, infertility, surgical intervention, including after successful insertion, spontaneous migration, spontaneous perforation, spontaneous organ damage, or infertility.

101. Despite the fact that Defendants knew or should have known that their product posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Mirena for use by consumers and continued to fail to comply with federal requirements.

102. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

103. It was foreseeable that Defendants' product, as designed, would cause serious injury to consumers, including Plaintiff.

104. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

105. Defendants' conduct as described above, including but not limited to their failure to adequately design, test, and manufacture, as well as its continued marketing and distribution of the Mirena IUD when they knew or should have known of the serious health risks it created and the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

106. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, and willful and wonton conduct, which warrants the imposition of punitive damages.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT V
BREACH OF EXPRESS WARRANTY

107. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

108. Defendants expressly warranted that their Mirena IUD was a safe and effective device for women seeking contraception, and did not disclose the material risks that Mirena could embed, migrate, cause perforation, organ damage, infertility, or require surgical intervention, including after successful insertion.

109. The representations were not justified by the performance of Mirena.

110. Members of the consuming public, including consumers such as Plaintiff, and her healthcare providers, were intended third party beneficiaries of the warranty.

111. Plaintiff and her healthcare providers reasonably relied on these express representations.

112. The IUD manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to the Plaintiff when used as recommended and directed, and these risks were not disclosed to Plaintiff or her healthcare providers.

113. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys'

fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT VI
BREACH OF IMPLIED WARRANTY

114. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

115. When Defendants designed, manufactured, marketed, sold, and distributed their Mirena IUD for use by the Plaintiff, Defendants knew of the use for which it was intended and impliedly warranted the product to be of merchantable quality and safe for such use and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

116. Plaintiff and her physicians reasonably relied upon the Defendants' representations of the product's merchantable quality and that it was safe for its intended use, and upon Defendants' implied warranty, including that it was in compliance with all federal requirements.

117. Contrary to such implied warranty, the Mirena IUD was not of merchantable quality or safe for its intended use, because the product was defective, as described herein, and it failed to comply with federal requirements.

118. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys'

fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT VII
FRAUD AND MISREPRESENTATION

119. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

120. Defendants falsely and fraudulently represented to the medical and healthcare community and to the Plaintiff, as well as to the FDA, and the public in general, that the product had been tested and was found to be safe for use.

121. The representations made by the Defendants were, in fact, false.

122. When these representations were made by the Defendants, they knew those representations to be false and/or willfully, wantonly, and recklessly disregarded whether the representations were false.

123. Defendants knowingly and intentionally made false representations of material fact to Plaintiff, including but not limited to claims that their IUD product was safe and/or that it had adequately disclosed all risks of use.

124. These representations were made by the Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing Plaintiff, the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and purchase the product, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff and the public in general.

125. When these representations were made by Defendants and when Plaintiff utilized the Mirena device, she and her physician reasonably believed them to be true and were unaware that they were false.

126. In reliance on these representations, Plaintiff was induced to, and did use the product, and her healthcare providers were induced to, and did prescribe and insert the product. As a result, Plaintiff sustained severe and permanent personal injuries including but not limited to significant pain, irritation and discomfort, economic damage, and other severe and permanent health consequences, notwithstanding the Defendants' knowledge of the risk of these injuries and side effects.

127. Defendants knew and were aware, or should have been aware that Mirena had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

128. Defendants knew or should have known that their product had a potential to, and would cause severe and grievous injury to the users of product, and that it was inherently dangerous in a manner that exceeded its inaccurate, and down-played warnings.

129. Defendants brought the Mirena IUD to the market and acted fraudulently, wantonly, and maliciously, to the detriment of the Plaintiff.

130. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or their failure to disclose their violations of federal requirements applicable to their product, Plaintiff used Mirena and

suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT VIII
CONSUMER FRAUD - VIOLATION OF CONSUMER PROTECTION STATUTES

131. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

132. Defendants used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts in connection with the sale, advertisement and promotion of its Mirena IUD, in violation of all applicable state consumer fraud statutes, with the intent that consumers, including Plaintiff and her physician, rely upon such concealment, suppression and omission, and for the purpose of influencing and inducing physicians and medical providers to prescribe it for patients/consumers such as the Plaintiff. By reason of the Defendants' unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff, were caused to suffer ascertainable loss of money and property and actual damages.

133. Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the Mirena IUD.

134. Defendants misrepresented and omitted material information regarding the Mirena IUD by failing to disclose known risks.

135. The Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the Mirena IUD.

136. Defendants' actions violated N.C. Gen. Stat. §§ 17-1.1, *et seq.*, and other applicable state consumer protection statutes.

137. Mirena is a "Product" within the meaning of these statutes, and at all times relevant to this action, Defendants conducted trade and commerce within the meaning of these statutes, and Plaintiff and Defendants are "persons" within the meaning of these statutes.

138. Defendants' statements and omissions were undertaken with the intent that the FDA, physicians, healthcare providers, and consumers, including Plaintiff, would rely on the Defendants' false and deceptive statements and omissions.

139. Plaintiff's physicians and healthcare providers prescribed Mirena to Plaintiff, who suffered ascertainable losses of money and property as a result of Defendants' fraudulent methods, acts, practices, and sale of Mirena.

140. Defendants, through their officers, directors, agents, representatives, managers, and employees, are the researchers, developers, designers, testers, manufacturers, inspectors, labelers, distributors, marketers, promoters, releasers, and sellers of Mirena into the stream of commerce.

141. This jurisdiction and North Carolina have enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that the Mirena IUD was fit to be used for the purpose for which it was intended, when the Defendants knew it was defective and dangerous, failed to properly warn of material risks associated with its use, and by other acts alleged herein.

142. Defendants engaged in the deceptive acts and practices to sell the Mirena IUD to the public, including Plaintiff.

143. As a direct and proximate result of the Defendants' violations of various consumer protection statutes, Plaintiff has suffered damages, for which she is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

144. As a direct and proximate result of Defendants' conduct, Plaintiff used the Mirena IUD and suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT IX
NEGLIGENT MISREPRESENTATION

145. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

146. Defendants, through their marketing and other actions, misrepresented that Mirena was safe and did not pose a risk of embedment, migration, perforation, organ damage, infertility, or surgical intervention, including after successful insertion.

147. Defendants made these misrepresentations to induce Plaintiff and others to use Mirena and Plaintiff's and other's healthcare providers to prescribe Mirena, to gain profit.

148. Given the information available to the Defendants, it was not reasonable for the Defendants to believe that their misrepresentations were true. Instead, Defendants knew or should have known their representations were false and that it should have conducted further tests and studies to measure the likelihood of embedment, migration, perforation, organ damage, infertility, and surgical intervention, including after successful insertion, and should have disclosed those risks to patients and healthcare providers, including Plaintiff and Plaintiff's healthcare providers.

149. Plaintiff and Plaintiff's healthcare providers reasonably relied on Defendants' misrepresentations.

150. In the absence of these misrepresentations, Plaintiff would not have used Mirena.

151. As a direct and proximate result of Defendants' conduct, Plaintiff used the Mirena IUD and suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT X
FRAUDULENT MISREPRESENTATION

152. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

153. Defendants' misrepresentations were made of a presently existing fact with knowledge that the representations were untrue.

154. Defendants intended for Plaintiff and her healthcare providers to rely on their misrepresentations.

155. Plaintiff and her healthcare providers reasonably relied on Defendants' misrepresentations and suffered an injury as a result.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT XI
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

156. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

157. The Defendants were negligent, as alleged herein.

158. As a result of Defendants' negligence, Plaintiff suffered serious emotional distress.

159. Defendants' negligence was the proximate cause and a substantial factor in causing Plaintiff's serious emotional distress in that she would not have suffered this distress absent injury caused by Defendants.

160. It was not reasonable to expect Plaintiff to suffer this distress.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT XII
UNJUST ENRICHMENT

161. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

162. Defendants are, and at all times relevant to this action was, the manufacturer, seller, and supplier of Mirena.

163. Plaintiff was prescribed and billed for Mirena for the purpose for which it was intended, and in reliance upon Defendants' representations of the safety and efficacy of the product.

164. Defendants have accepted payments from Plaintiff, other consumers, and third party payors for the purchase of Mirena, totaling hundreds of millions of dollars in revenue and financial gain from the sale of the unsafe product.

165. Plaintiff did not receive the safe and effective product for which she was billed, and equity therefore demands that Defendants be disgorged of their profits received from sales of the defective products and its own deception regarding the safety and efficacy of the drug.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

PRAYER FOR RELIEF

Plaintiff respectfully requests judgment against Defendants on each of the above counts as follows:

a. Compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and

permanent personal injuries, healthcare costs, medical monitoring, together with all interest and costs as provided by the law;

b. Punitive and exemplary damages for the wanton, willful, fraudulent, and reckless acts of Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiff, in an amount sufficient to punish Defendants and deter future similar conduct;

c. Treble damages for violation of consumer protection statutes;

d. Plaintiff's attorney fees;

e. Plaintiff's costs of the proceedings; and

f. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

The Plaintiff hereby demands a trial by jury on all counts and as to all issues.

Dated: January 31, 2014

Respectfully Submitted,

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